

SEP 26 2008

K081808
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SECTION 11

510(k) Summary Prepared June 24, 2008

Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
1230 Shorebird Way
Mountain View, California 94043

Contact Person: Shelly Pearce
Telephone: (650) 694-5988
Fax: (650) 694-5580

Submission Date: June 24, 2008

Modified Device Name: AcuNav V Ultrasound Catheter

Common Name: Diagnostic Ultrasound Catheter

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology
Ultrasonic Imaging Catheter ; 21C FR # 892.1200; Product Code OBJ

A. Legally Marketed Predicate Devices

The modified AcuNav Diagnostic Ultrasound Catheter is substantially equivalent to the original AcuNav Ultrasound Imaging Catheter.

B. Device Description:

The AcuNav V has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
 - EN/IEC 60601-1
 - EN/IEC 60601-1-1
 - EN/IEC 60601-1-2
- IEC 61157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility
- ISO 14971 Risk Management
- ISO 11607 Packaging for terminally sterilized medical devices

The AcuNav V catheter is to be used only on systems with which it has been tested and found compatible. Each of these system/transducer combinations shall be cleared through the 510(k) process and have a subsequent special report submitted.

C. Intended Use

The Acuson AcuNav V Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. Performance Data

The AcuNav modifications are verified and validated according to the company's design control process.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2008

Siemens Medical Solutions USA, Inc.
c/o Ms. Shelly Pearce
Regulatory Affairs
P.O. 7393
1230 Shorebird Way
Mountain View, CA 94039

Re: K081808

Trade Name: ACUSON AcuNav V 10F Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: September 5, 2008
Received: September 5, 2008

Dear Ms. Pearce:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality


Page 2 - Ms. Shelly Pearce

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman

 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 6

Diagnostic Ultrasound Indications for Use Form

510(k) Number: K081808

Device Name: **ACUSON AcuNav V 10F Ultrasound Catheter**

Indications for Use: The AcuNav™ V Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Vascular)										
Intraoperative (Neurological)										
Pediatric										
Small Organ (Specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		p*	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal		P	P	P	P	P	P		p*	
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Intra-Cardiac)		P	P	P	P	P	P		p*	

P=Previously cleared by the FDA.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,

B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Donna R. Vedner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081808

SECTION 7 Intended Use of the Device

510(k) Number (if known): K081808

Device Name: AcuNav V Ultrasound Catheter, 10F

Indications For Use:

The Acuson AcuNav V Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachon
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081808

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